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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/464,902	12/16/1999	WILLIAM C. OLSON	57906-AJPW/S	8227

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EXAMINER

LE, EMILY M

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 04/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/464,902

Applicant(s)

OLSON ET AL.

Examiner

Emily Le

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 78-101 is/are pending in the application.
- 4a) Of the above claim(s) 78-86, 89-90 and 96-97 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 87-88, 91-95, and 98-101 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in Applicant's 01/26/2004 response is acknowledged. The traversal is on the ground(s) that the Examiner has misinterpreted the claims. This is found persuasive. In view of the explanation that is presented by Applicant, on page 12 of Applicant's response, the previously presented Supplemental Restriction requirement, mailed 10/21/2003 is hereto withdrawn. Therefore, claims 87-88, 91-95, and 98-101 are currently under examination, all of which are drawn to the originally elected Group VI with traverse, in Applicant's March 29, 2003 response to the September 25, 2002 Restriction Requirement.

The Examiner previously addressed Applicant's traversal of Group VI in the Supplemental Restriction. However, because the noted office action is now withdrawn, the following is the Examiner's response to Applicant's traversal arguments of the Restriction Requirement mailed 09/25/02 (still in effect):

Applicant's election with traverse of Group VI in Paper No. 8, mailed 03/29/03, is acknowledged. The traversal is on the ground(s) that the restriction is improper because Groups V-VII are not independent from one another and that a restriction can only proper if the separated inventions are independent AND distinct from one another while quoting from MPEP § 802 and 35 U.S.C § 121. This is not found persuasive. Applicant is taking the teachings of the MPEP out of context. MPEP § 806, states that a restriction is proper if the inventions are able to support separate patents and they are either independent (MPEP § 806.04 - § 806.04(i)) or distinct (MPEP § 806.05 -

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§806.05(i)). In the instant case, each Groups can support a separate patent and that are distinct from one another for each groups are directed Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

The requirement is still deemed proper and is therefore made FINAL unless Applicant admits that the Groups are obvious variants of each other.

Status of Claims

2. Claims 78-101 are pending. Claims 78-86, 89-90, and 96-97 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Applicant's 01/26/2004 and 03/23/2003 response. In view of Applicant's election of Group VI in response to the Restriction Requirement, mailed 09/25/2002, claims 87-88, 91-95, and 98-101 are currently under examination.

Specification

3. The disclosure is objected to because of the following informalities: the bridging paragraph of pages 13-14 discusses a deposit, however, it is unclear what has been deposited. Is it the antibodies that has been deposited or the hybridomas that produce

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the antibodies? It is unclear what Applicant has deposited under the listed accession numbers.

Appropriate correction is required.

Information Disclosure Statement

4. The information disclosure statements filed 06/20/00, 06/18/01, and 09/04/03 fail to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 87-88, 91-95, and 98-101 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel biological materials, specifically anti-CCR5 monoclonal antibodies designated with ATCC Accession No. HB-12610, 12605, 12606, 12607, 12608, and 12609. Since the biological materials are specifically recited in the claims, and the components are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise readily

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available to the public. If the biological materials are not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of biological materials.

The specification does not disclose a repeatable process to obtain the biological materials and it is not apparent if the biological materials are readily available to the public. It appears that Applicant has deposited biological materials, p. 13 of the specification, but it is not clear what has been deposited. There is no indication in the specification as to public availability. If the deposit is made under the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific biological materials have been deposited under the Budapest Treaty and that the biological materials will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. § 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

- During the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- All restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- The deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is

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longer;

- A test of the viability of the biological material at the time of deposit will be made (see 37 C.F.R. § 1.807); and
- The deposit will be replaced if it should ever become inviable.

7. Claims 87-88, 91-95, and 98-101 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acid molecule that encodes 6 CDR regions of the deposited antibodies, does not reasonably provide enablement for nucleic acid molecule that encodes less than 6 CDR regions of the deposited antibodies. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In *Genentech Inc. v. Novo Nordisk* 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997); *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); See also *Amgen Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir. 1991); *In re Fisher* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Further, in *In re Wands* 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court stated:

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman* [230 USPQ 546, 547 (Bd Pat App Int 1986)]. They include

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(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

It is well established in the art that the formation of an intact antigen-binding site generally requires the association of the complete heavy and light chain variable regions of a given antibody, each of which consists of three CDRs which provide the majority of the contact residues for the binding of the antibody to its target epitope. The amino acid sequences and conformations of each of the heavy and light chain CDRs are critical in maintaining the antigen binding specificity and affinity which is characteristic of the parent immunoglobulin. It is expected that all of the heavy and light chain CDRs in their proper order and in the context of framework sequences which maintain their required conformation, are required in order to produce a protein having antigen-binding function and that proper association of heavy and light chain variable regions is required in order to form functional antigen binding sites. Even minor changes in the amino acid sequences of the heavy and light variable regions, particularly in the CDRs, may dramatically affect antigen-binding function as evidenced by Rudikoff et al (Proc Natl Acad Sci USA 1982 Vol 79 page 1979). Rudikoff et al. teach that the alteration of a single amino acid in the CDR of a phosphocholine-binding myeloma protein resulted in the loss of antigen-binding function.

It is unlikely that the nucleic acid molecule that encodes less than the full complement of CDRs from the heavy and light chain variable regions of the antibodies that is produced from the deposited hybridomas, which is instantly claimed, have the required binding function and activity. The specification provides no direction or guidance regarding how to produce nucleic acid molecule that encodes less than the full complement of CDRs from the heavy and light chain variable regions of the antibodies that is produced from the deposited hybridomas nor has it taught one of ordinary skill in the art how to use such. Undue experimentation would be required to produce the invention that commensurate with the scope of the claims from the written disclosure alone.

Therefore, in view of the lack of guidance in the specification and in view of the discussion above one of skill in the art would be required to perform undue experimentation in order to practice the claimed invention.

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wrigtht*, 999 F. 2d 1557, 1562, 27 USPQ 2d 1510, 1513 (Fed. Cir. 1993).

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

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and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 87-88, 91-95, and 98-101 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-13 of copending Application No. 10/081,128.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and the cited application are directed to nucleic acids that encode CDR regions of antibodies that bind to CCR5, anti-chemokine receptor 5 (CCR5) monoclonal antibody.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

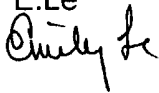
Conclusion


No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

E.Le



Shanon Foley
Patent Examiner, AU 1648